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March 23, 2015

U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.
No. 11 Civ. 8196 (CM) (JCF)

Dear Judge McMahon:

We represent Defendant Novartis Pharmaceuticals Corporation ("Novartis") in the above-referenced matter. We write in response to the letter (the "Pls. Letter") (ECF No. 373) that the United States (the "Government") filed on March 17, 2015, on behalf of itself, the 11 intervening states (the "Intervening States") and the Relator (collectively, "Plaintiffs"), seeking a two-month extension of the discovery deadlines and a corresponding adjournment of the trial-ready date or, in the alternative, an order precluding Novartis from advancing an advice-of-counsel defense at trial.

After a nearly two-and-a-half-year pre-suit investigation and more than a year of additional post-intervention discovery, during which time Novartis has produced over 60 million pages, Plaintiffs now seek to use Novartis's waiver of attorney-client privilege as to approximately 350,000 pages—less than 0.6% of the total pages produced—as a reason for extending the deadlines set by the Court. When Plaintiffs approached Novartis about an extension, Novartis stated that it intended to meet the current schedule but offered to work together with Plaintiffs on a proposal that would extend the fact and expert discovery deadlines while keeping the trial-ready date. Plaintiffs rejected that compromise, but Novartis remains prepared to meet the Court's schedule and, for the reasons set forth below, respectfully requests that the Court deny the relief Plaintiffs seek.

As a side matter, should the Court grant Plaintiffs' extension request, I would like to advise the Court that I have another trial that is presently scheduled to begin on September 22, 2015, that has been scheduled since August 2014. This likely means that I would be unavailable to begin the Novartis trial until November 2015.

I. Background

We believe it is helpful to describe what has transpired between the parties during the past year in order to give context to the merits of the instant dispute.

A. The March 14, 2014 Initial Conference and Subsequent Discovery

During the nearly two-and-a-half-year pre-suit investigation in this case, the Government demanded that Novartis collect, review and produce over 15 million pages of material, and the Government took testimony from 19 former and current Novartis employees, as well as numerous third party personnel at specialty pharmacies. At the initial conference on March 14, 2014, the Court made clear to the Government that its time to seek additional discovery had passed: "You've been looking at this for two and a half years, you would continue to look at it if I hadn't stopped you. As far as I'm concerned, you know what you've got to know. You're not going to get extra time. You are on the hook." (Conf. Tr. 53:1-5, Mar. 14, 2014, ECF No. 159.) The Government replied: "Your Honor, we are certainly not asking for extra time." (Conf. Tr. 53:6-7.)

Nevertheless, since the March 2014 conference, the Government has propounded 43 additional requests for production, and the Relator (who has access to all documents previously produced to the Government) has propounded 82 additional requests for production, including one request as recently as February 17, 2015. In response to these requests (and other post-investigation requests), Novartis has made over 65 additional productions since March 2014, totaling more than 45 million pages, bringing the document production in this case to date to more than 60 million pages.

It is these continuing requests for production that have made it challenging for the parties to meet the discovery schedule set by the Court, not Novartis's decision to waive privilege.

B. Novartis's Decision To Waive Attorney-Client Privilege with Respect to Exjade

The Government's assertion that Novartis was dilatory in asserting its intent defense is unfounded. (Pls. Letter at 1.) It is true that when the Government first asked in June and July 2014 whether Novartis planned to rely upon "advice of counsel", Novartis's lawyers responded that Novartis "does not currently intend to assert an advice of counsel defense". However, counsel made clear that if Novartis's "view on that issue changes, we will advise you in sufficient time for the United States to take necessary discovery regarding that defense". (Letter from Gov't and Intervening States, Ex. A at 1-2, Feb. 27, 2015, ECF No. 351-1.)

Since July, there have been significant developments that Novartis took into account in reconsidering its waiver decision. On August 7 and September 4, 2014, the Court denied Novartis's motions to dismiss the Government's complaints, rejecting Novartis's argument that the Government was required (and failed) to plead that the alleged kickback schemes "caused" doctors to prescribe Myfortic and patients to order refills of Exjade. (Mem. & Order at 29, Aug. 7, 2014, ECF No. 227; Mem & Order at 27, Sept. 4, 2014, ECF No. 234.) In addition, as a result of Magistrate Judge Francis's November 24 decision on Novartis's motion to compel production of documents related to the Government's own adherence programs (and the

Government's subsequent December 8 decision to drop its unjust enrichment claims rather than hand over those documents), Novartis did not receive evidence upon which it had intended to rely to demonstrate Novartis's lack of intent in designing a similar Exjade program without having to waive privilege. (See Mem & Order at 12, Nov. 24, 2014, ECF No. 307 (Novartis wanted to use the evidence to "undermine the argument that Novartis' conduct was 'willful' as required by the Anti-Kickback Statute".); Letter from Gov't and Intervening States, Dec. 8, 2014, ECF No. 309 ("Pursuant to that direction ['that, if the Government and the Litigating States abandon their unjust enrichment claims, then the discovery sought by Novartis pursuant to its motion to compel would be irrelevant'], the Government and Litigating States elect to dismiss their unjust enrichment claims."); see also Conf. Tr. 21:3-21, Mar. 14, 2014, ECF No. 159 (Novartis explained that "there will be . . . a ton of evidence to show that the government itself proclaims the virtues of adherence programs . . . .").)

Novartis therefore revisited the waiver question and ultimately determined that evidence reflecting legal advice in connection with the Exjade adherence activities challenged by Plaintiffs was key to demonstrating Novartis's lack of intent. But the decision to waive privilege is a difficult one, and Novartis needed to consider that decision carefully and at various levels of the organization, while at the same time continuing to respond to the multiple document requests and deposition notices it was receiving. Novartis did not finally reach a decision until February 16, 2015, and it notified Plaintiffs of its decision the very next day.

Indeed, in an effort to inform Plaintiffs of the decision sooner rather than later, Novartis communicated its waiver decision to Plaintiffs prior to completing the collection and review of all relevant documents. As a result, Novartis expressly informed Plaintiffs that it was uncertain about the volume of the waiver production but that it did not anticipate the volume to be significant and expected to complete the production by mid-March. (Letter from Novartis, Ex. A at 6, Mar. 2, 2015, ECF No. 357-1 ("At this point, we are still in the process of assessing the volume of documents, so we are unable to provide you with an estimate of total volume at this time. . . . While this information may not be as precise as you would like, please understand that, because our priority was to inform you of our waiver decision as quickly as possible, we have not had an opportunity to compile a comprehensive set of documents.").) Plaintiffs nonetheless now represent to the Court that Novartis "knew the approximate volume and should have been upfront about this with plaintiffs and the Court". (Pls. Letter at 3.) That claim simply is not true.

C. The March 4, 2015 Hearing Before Judge Francis and the March 13, 2015 Production

On February 27, 2015, the Government filed a letter with Judge Francis, seeking expedited production of Novartis's waiver documents. (Letter from Gov't and Intervening States at 2, ECF No. 351.) In that letter the Government raised the same argument it now raises here—that Novartis's decision to waive privilege was dilatory. (Id. at 1.) On March 3, 2015, the Relator filed a letter with Judge Francis claiming that "Novartis plans to improperly 'cherry pick' the documents it will produce". (Letter from Relator at 1, ECF No. 359.) The Relator requested that the Court order Novartis to produce a greater set of documents and that "Novartis identify, by BATES number, each document containing legal advice on which Novartis intends to rely for its defense". (Id. at 3.)

On March 4, the parties had a teleconference with Judge Francis. Judge Francis did not find Novartis's decision to waive privilege to be belated. After issuing an Order regarding inadvertent waiver pursuant to Federal Rule of Civil Procedure 502(d), Judge Francis set March 13 as the date to produce the documents for which Novartis was waiving its attorney-client privilege. (Order, Mar. 4, 2015, ECF No. 362.[1]) Novartis also agreed to provide BATES numbers for the documents on which it might rely for its advice of counsel defense. Judge Francis found to be "fully satisfactory" "on a theoretical level" Novartis's representation that it would produce any document that directly implicates the advice regarding the challenged Exjade-related activities. (Teleconf. Tr. 17:8-9, Mar. 4, 2015, ECF No. 369.)

On March 13, 2015, Novartis (i) produced waiver documents that concerned the Exjade-related activities that Plaintiffs challenge; (ii) identified the documents on which it may rely for its advice of counsel defense; and (iii) produced a revised privilege log, a second privilege log and the corresponding documents. (Letter from Novartis at 1-2, Mar. 13, 2015, ECF No. 382-5.)

On March 17, 2015, after receiving an email from the Government indicating that it planned to approach the Court for an extension, Novartis met telephonically with counsel for Plaintiffs. Novartis explained that it did not see the need to move all deadlines back two months and offered to work with Plaintiffs to propose changes to the schedule that would extend the internal fact discovery and expert deadlines but hold the trial-ready date. Plaintiffs rejected that proposed solution.

II. Argument

Scheduling orders "may be modified only for good cause and with the judge's consent". Fed. R. Civ. P. 16(b)(4). "The burden of demonstrating good cause rests with the movant." Ritchie Risk-Linked Strategies Trading (Ireland), Ltd. v. Coventry First LLC, 282 F.R.D. 76, 79 (S.D.N.Y. 2012). "The Rule 16(b)(4) 'good cause' inquiry is primarily focused upon the diligence of the movant in attempting to comply with the existing scheduling order and the reasons advanced as justifying that order's amendment." Id. Plaintiffs have failed to demonstrate good cause to extend the discovery period until June 15 and disrupt the current trial schedule.

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[1] Plaintiffs contend that "Novartis refused to . . . participate in meet-and-confer" (Pls. Letter at 2) regarding specific claims of privilege with respect to particular documents. That is misleading. In response to the referenced challenge to particular documents, Novartis (i) dropped one of the privilege claims it had asserted and subsequently provided the previously redacted document in unredacted form; (ii) explained its grounds for privilege with respect to the remaining documents at issue; (iii) offered to meet and confer if Relator continued to dispute these privilege calls; and (iv) asked that future challenges to particular documents be postponed for approximately one week, during which time Novartis would re-review its previous privilege determinations. (See Novartis Ex. 1 at 2.)

A. Plaintiffs Failed To Demonstrate Diligence

Plaintiffs have not demonstrated diligence in attempting to comply with the existing scheduling order. Despite the Court's admonition during the March 14, 2014 conference, Plaintiffs have continued, late into discovery, to propound requests for production of documents and to demand searches from additional custodians that they have known about for years, including requests as recently as February 13 (requesting three additional Exjade custodians), February 17 (eighty-second request for production of documents) and February 26, 2015 (requesting four additional Myfortic custodians). (See Novartis Ex. 2 at 2, 4.) Likewise, on February 17, 2015, Relator moved to compel the removal of thousands of redactions that Novartis had made years before (during the investigation) for non-responsive information about drugs that are undisputedly not at issue in this litigation. Relator has had those documents for months, but moved to compel their unredacted form just last month. Rather than litigate the issue, Novartis chose to remove the non-responsiveness redactions, review the thousands of documents for privilege and produce them along with a log indicating any claims of privilege. All of these requests are completely unrelated to Novartis's waiver, and they have contributed significantly to the number of additional documents Plaintiffs complain they must review. (Pls. Letter at 2.)

Moreover, the volume of Novartis's waiver production is itself a product of Plaintiffs' demand for more documents. In early February, the Relator demanded privileged documents related to Novartis's compliance with the Anti-Kickback Statute and False Claims Act, based on a flawed argument that statements in Novartis's September 2014 motion to compel had implicitly waived privilege. (See Novartis Ex. 3 at 2-4.) After Novartis independently decided to waive privilege and made its initial waiver production, Plaintiffs complained that the waiver was too narrow and that Novartis was "cherry pick[ing]". (Letter from Relator at 1, Mar. 3, 2015, ECF No. 359; see also Teleconf. Tr. 14:14-15, Mar. 4, 2015, ECF No. 369 ("in practice, Novartis is interpreting this waiver incredibly narrowly.").) In response to Plaintiffs' demands, Novartis broadened the scope of its waiver, which necessarily resulted in a larger document production. Now that Novartis has already produced its sensitive documents, Plaintiffs somehow complain, on the one hand, that the waiver contains too many documents and simultaneously, on the other hand, that the waiver is still too narrow. (See, e.g., Pls. Letter at 2 (Novartis's "massive production of documents" was also "unfairly narrow and selective".).) Still not satisfied, the Government has also made a motion to expand the waiver to Myfortic. (See Letter from Gov't at 4, Mar. 16, 2015, ECF No. 372.) Plaintiffs cannot manufacture a basis for an extension by using as a pretext Novartis's compliance with their unrelenting demand for documents.

Contrary to the representation that Plaintiffs "have proceeded with depositions of Novartis employees who did not appear to be involved with seeking or implementing legal advice" (Pls. Letter at 3), Plaintiffs have refused to proceed with the deposition of any Novartis witness noticed in connection with the Exjade claims. Indeed, the Government has adjourned a total of 10 depositions, including depositions of Novartis personnel in scientific and medical positions who were not involved in seeking or receiving legal advice. (Letter from Novartis, Ex. A at 1, 3, Mar. 2, 2015, ECF No. 357-1.)

The Government even canceled the previously scheduled March 27, New York deposition of David Epstein, the Division Head of Novartis Pharmaceuticals, who lives and works in Basel, Switzerland, even though only 221 tangentially-related documents from the March 13 waiver production contain his name and the deposition had been on the calendar for nearly two months. (Novartis Ex. 4 at 1-2.)

B. Plaintiffs Have Not Explained Why Their Resources Are Insufficient To Meet the Discovery Deadline

While Plaintiffs have described the task at hand, they have not described why their resources are insufficient to complete the task before June 15 (or even by April 17, for that matter). Plaintiffs consist of 13 parties—which include the United States government, 11 states and the Relator, who is represented by two law firms. Plaintiffs represented to the Court that they would cooperate with each other and "coordinate for efficiency in discovery". (Conf. Tr. 52:9-13, Mar. 14, 2014, ECF No. 159.) There is no good reason why these 13 parties need until June 15 to complete remaining discovery.

Novartis has spent millions of dollars and worked diligently to respond to Plaintiffs' flood of post-investigation discovery demands and to keep the schedule. Novartis is willing to do whatever it takes to meet the Court's schedule, including double- or triple-tracking depositions. All parties involved in this dispute have the resources to accomplish the schedule that has been in place for sixth months.

C. Plaintiffs' Alternative Relief Is Extremely Prejudicial to Novartis, Inadequately Raised and Inappropriate

Now that Novartis has produced thousands of privileged documents in order to negate the element of intent, Plaintiffs seek an alternative of precluding Novartis from asserting the defense for which it waived the privilege. First, it is more than a month since Novartis announced it was waiving the attorney-client privilege, three weeks since it produced the first privileged documents and one week since it substantially completed its production of waiver-related documents.[2] It would be extremely prejudicial for Novartis, which has already disclosed

[2] Pursuant to Judge Francis's Order, Novartis produced substantially all the documents related to its privilege waiver by March 13. In its most recent letter to the Court, submitted March 20, the Government complains about 13 documents (just 15 pages) that were mistakenly omitted from the March 13 production. Novartis produced these 15 pages to the Government on March 18, as soon as Novartis realized the error, and it explained in its cover letter that the error was inadvertent. There is no reason that 15 pages of material should result in a letter to the Court; indeed, this is precisely the type of posturing that has created the discovery delays that Plaintiffs are now attempting to use as the reason to extend the current schedule. We anticipate that during the next few weeks there will be similar small productions of additional waiver materials that were either omitted in error or identified during limited follow-up searches. We hope that the productions will not prompt similar letters to the Court. Finally, we note that on Friday, March 20, Novartis produced the last installment of its privilege log, together with redacted documents referenced in the log, as well as documents that were previously on the log but over which Novartis is no longer claiming privilege. Novartis does not consider these

privileged documents in order to make a defense, to be deprived of the ability to make that defense. Second, Plaintiffs have not adequately raised preclusion because they make no argument and cite no law in support of their preclusion request. See LG Electronics, Inc. v. Wi-LAN USA, Inc., No. 13-CV-2237, 2014 WL 3610796, at *3 n.3 (S.D.N.Y. July 21, 2014).

* * *

For the foregoing reasons, we respectfully request that the Court deny the relief sought by Plaintiffs.

Respectfully,

Evan R. Chesler/DH

Evan R. Chesler

Hon. Colleen McMahon
United States District Judge
Southern District of New York
500 Pearl Street, Room 1640
New York, NY 10007

VIA ECF

Copies w/ encls. to:

All Counsel of Record

VIA EMAIL AND ECF

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materials part of its Exjade waiver production, but acknowledges that certain documents were removed from the log as a result of the waiver.